

Appln No.: 09/824,587  
Amendment Dated: May 18, 2005

### REMARKS/ARGUMENTS

This amendment is filed with a request for Continuing Examination in lieu of an Appeal Brief, and in response to mailed September 8, 2004. Reconsideration and further examination are respectfully requested.

Claims 21-50 stand rejected for failing to comply with the written description requirement of 35 USC § 112. Applicants traverse this rejection.

Claim 20 has been amended so that the first and second state are defined in terms of having a first or second set of "forms" as opposed to "isoforms". Claim 20 also states that "the first set of forms differs from the second set of forms as a result of containing different forms of the analyte in different relative amounts." Taking by way of example, an analyte X, which exists in two forms, X<sub>1</sub> and X<sub>2</sub>, the first and second state as thus defined might be

State 1	State 2
X <sub>1</sub>	X <sub>2</sub>
50% X <sub>1</sub> 50% X <sub>2</sub>	X <sub>2</sub>
X <sub>1</sub>	50% X <sub>1</sub> 50% X <sub>2</sub>
20% X <sub>1</sub> 80% X <sub>2</sub>	80% X <sub>1</sub> 20% X <sub>2</sub>

where the specific numbers are merely made up examples. In each of these case, there are different forms present in different relative amounts, such that the two states are different. This is the same as the original description in which the states were said to differ from one another "in the nature and/or amount of one or more forms present" (Page 2, lines 23-24).

The first step of the recited method is "obtaining first and second assay samples containing the analyte, said first and second assay samples being either aliquots of a single sample or contemporaneous samples from the same source" is based on the disclosure as filed, including *inter alia*, the disclosure at Page 10, lines 21-29.

The second step of the method calls for "performing a first specific binding assay on the first assay sample by reacting the first assay sample with a first binding agent to form a first binding agent/analyte complex, and then subsequently reacting the first binding agent/analyte complex with a second binding agent to form a first binding agent/analyte/second binding agent complex." This type of assay is referred to in the application as a "two-step assay," and is described on Page 2, line 25- Page 3, line 2.

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The third step in the method of claim 20 is "performing a second specific binding assay on the second assay sample by reacting the second assay sample substantially simultaneously with the first binding agent and the second binding agent to form a first binding agent/analyte/second binding agent complex." This type of assay is referred to in the application as a "one-step assay," and is described on Page 3, lines 3-10.

The final two steps of the method of claim 20 call for "determining the amount of first binding agent/analyte/second binding agent complex formed in the first specific binding assay and the second specific binding assay" and comparing these amounts. Claim 20 further states that "at least one of the first and second binding agents has a different specificity for the forms of the analyte, whereby the amount of first binding agent/analyte/second binding agent complex formed in the first and second specific binding assays differs depending on the state of the analyte in the sample." This language is fully supported on Page 3, lines 10-13 and throughout the specification.

Given the fact that the language of the claims is fully supported in the specification, Applicants do not understand the basis for the written description rejection. In the rejection, the Examiner states that "the specification does teach that these two assays differentiate between a first and second state of an analyte," and goes on to discuss Example 3 from the specification. (Office Action, Page 3). This argument is not understood.

In Example 3, FSH is tested. FSH exists in two states: one characteristic of a menopausal condition and one characteristic of a fertile or pre-menopausal condition. The Examiner acknowledges that in Example 3 a differentiation between a pre-menopausal condition and a post-menopausal condition is made, but somehow fails to equate this to differentiating between the associated states of the FSH hormone.

The Examiner states that "the result do not show that in one set of sample[s], for example D14, a first state and a second state of FSH is differentiated." This, however, is not what the claim requires. The claim requires that the analyte (for example FSH) exist in at least two states, which it does, that two tests are performed, on a sample, and that based on a comparison of these two tests (which may be done by taking a ratio) one can tell the difference (or differentiate) between the two choices for the state in which the analyte exists.

The Table on Page 18 of the application shows results for 8 samples taken from a fertile woman, and 9 samples taken from a post-menopausal woman on consecutive days. For clarification, there is no relationship between D14 in the first set and D14 in the second set. This merely is an arbitrary reference to the day in the collection cycle. The results from the two women are clearly different, such that taking a single sample one would now whether to categorize the sample as pre or post-menopausal. This is what the claims require, and it is what the example shows.

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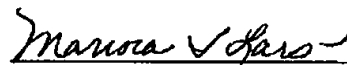
For this reason, Applicants submit that the claimed invention is fully described by a "written description" as required in 35 USC § 112, first paragraph. Withdrawal of the rejection is requested.

The Examiner also rejected claims 21-50 for lack of enablement under 35 USC § 112, first paragraph. The Examiner again distinguishes between a pre-menopausal and a post-menopausal state of a patient on the one hand, and the states of the analyte, such as FSH which are characteristic of these patient conditions, but does not explain why. Both the distinction that the Examiner draws and the lack of explanation are improper.

In view of the foregoing, Applicants submit that the rejection for lack of enablement should be withdrawn.

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited. However, if the rejection is to be maintained, Applicants request an interview to discuss the basis for the Examiner's concerns so that clarification can be provided. It is noted that the Examiner has refused one request for an interview in this case because it was too close to the end of the quarter, and failed to return a telephone call in a second attempt to schedule an interview.

Respectfully Submitted,



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